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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Minotti, et al.

Examiner: Khare, D.

Application No.: 09/954,953

Group Art Unit: 1623

Filed: September 18, 2001

Docket: 1188-37

Confirmation No.: 8528

For: METHOD FOR REDUCING TOXICITY OF COMBINED CHEMOTHERAPIES

Dated: June 24, 2002

I hereby certify this correspondence is being deposited with United States Postal Service as first class mail, postpaid in an envelope, addressed to: Commissioner of Patents, Washington, D.C. 20231.

Dated: June 24, 2002

Signature: Barbara Kemmlein

Commissioner for Patents
Washington, DC 20231-0001

AMENDMENT AND RESPONSE PURSUANT TO 37 C.F.R. §1.111

Sir:

This is in response to the Office Action dated February 5, 2002, a reply to which is due July 5, 2002, with a two-month extension of time. In view of the amendments and remarks below, reconsideration is respectfully requested.

Applicants' Response to Rejection of Claims 1-13 and 17 Under 35 U.S.C. §112

Claims 1-13 and 17 have been rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention under 35 U.S.C. §112, second paragraph. Specifically, the Action states that claims 1 and 17 are allegedly "vague and indefinite for stating 'treatment/chemotherapeutic treatment of cancer' as it is unclear as to what is intended with treatment of cancer." This rejection is respectfully traversed.

It is well understood in the art that the treatment of cancer includes the elimination of cancerous tissue. The methods of the present invention are capable of treating a variety of cancers. The application specifically mentions some of particular significance, such as lung, ovarian and breast cancers, however, the invention is not so limited. Doxorubicin and the taxanes paclitaxel and docetaxel are known to treat a variety of cancers. The methods of the present invention will treat these as well. Therefore, the terms "treatment of cancer" and "chemotherapeutic treatment of cancer" are sufficiently definite for the purposes of Section 112, second paragraph. Consequently, reconsideration and withdrawal of the rejections under Section 112 are respectfully requested.

Applicants' Response to Rejection of Claims 1-17 Under 35 U.S.C. §102(b)

Claims 1-17 have been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by articles by Gianni et al. ("Gianni") and Sparano. These rejections are respectfully traversed on the grounds that neither Gianni nor Sparano discloses every limitation of the claims of the present invention. Specifically, neither Gianni nor Sparano discloses the use of 4-desacetyl-4-methylcarbonate taxol in the treatment of cancer.

The therapies discussed by Gianni and Sparano include the combination of doxorubicin and either paclitaxel, commercially available as Taxol®, or docetaxel, commercially available as Taxotere®. Both compounds are taxane derivatives. Gianni's article is limited to the use of paclitaxel in combination with doxorubicin as a treatment for cancer, while Sparano's article includes disclosure of both paclitaxel and docetaxel. Although Sparano does mention the use of Taxanes in combination, this is in reference to the selection of either paclitaxel or docetaxel. Disclosure of 4-desacetyl-4-methylcarbonate taxol in combination with doxorubicin is absent in both articles. Therefore, both Gianni and Sparano fail as effective references under Section 102.

In addition, there is no teaching or suggestion that any taxane in combination with doxorubicin would provide a cancer treatment without increasing the cardiotoxicity of doxorubicin. As stated in the specification at page 1, lines 17-30, the combination of

doxorubicin and paclitaxel as a treatment is limited to dosing under 500 mg/m^2, in order to decrease the incidence of cardiotoxic byproducts. Studies of docetaxel in combination with doxorubicin have also been conducted, but while they report a low incidence of cardiotoxicity, only a small number of patients received doses higher than 360-400 mg/m^2.

Neither Gianni, nor Sparano discloses the use of 4-desacetyl-4-methylcarbonate taxol in combination with doxorubicin. Also, while taxanes are disclosed, they are limited to paclitaxel and docetaxel, both of which lead to potential problems with cardiotoxicity when used in combination with doxorubicin. There is no disclosure, teaching, or suggestion that 4-desacetyl-4-methylcarbonate taxol when used in combination with doxorubicin as in the present invention would eliminate the cardiotoxicity problem. Therefore, reconsideration and withdrawal of the rejections under Section 102 are appropriate and respectfully requested.

Applicants respectfully submit that the application is in condition for allowance and favorable action is therefore solicited. Should the Examiner have any questions, the undersigned will be pleased to address them by telephone.

Respectfully submitted,

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